

## 1.2 IN THE CLAIMS

*Please amend the claims to read as follows:*

1. (Currently Amended) A method of preparing aggregates of porcine pancreatic islets and porcine Sertoli cells capable upon implantation into a recipient, of producing insulin *in vivo*, including or comprising the steps of :
  - 1) isolation ofisolating porcine islet cells from the pancreas of donor piglets,
  - 2) isolation ofisolating porcine Sertoli cells from the testes of donor piglets,
  - 3) culturing the islet cells together with the Sertoli cells,
  - 4) formation of the aggregates.
  - 3) culturing the Sertoli cells for at least 1 day;
  - 4) adding the isolated porcine islet cells to the cultured Sertoli cells at a predetermined ratio;
  - 5) co-culturing the islet cells and Sertoli cells for at least 1 day;
  - 6) scraping the Sertoli cell layer over the islets to form aggregates; and
  - 7) culturing the aggregates for up to 24 hours.
2. (Currently Amended) AThe method of claim 1, wherein said aggregate is a combination of islet:sertoli cells in a predeterminingpredetermined ratio of from about 1:20,000 to about 1:100.
3. (Currently Amended) AThe method of claim 2, wherein said ratio is between about 1:2,000 toand about 1:4,000.
4. (Currently Amended) AThe method of any one of the preceding claimsclaim 1, wherein

said co-culturing step 5) is over a time period of from between about 3 to and about 7 days.

5. (Currently Amended) ~~A~~The method of claim 4, wherein ~~thesaid~~ time period is ~~for~~about 5 days.
6. (Currently Amended) ~~A~~The method of ~~any one of the preceding claims~~claim 1, wherein said isolation of the islets is followed by purification of the islets.
7. (Currently Amended) ~~A~~The method of claim 6, wherein the isolation and purification of the islets together comprise ~~or include~~ the steps of:
  - a) surgical removal;
  - b) collagenase digestion; and
  - c) washing and culturing of the islets.
8. (Currently Amended) ~~A~~The method of claim 7, wherein said collagenase digestion involves Liberase H and Xylocaine.
9. (Currently Amended) ~~A~~The method of ~~any one of the preceding claims~~claim 1, wherein said isolation of the Sertoli cells is followed by purification of the Sertoli cells.
10. (Currently Amended) ~~A~~The method of claim 9, wherein said isolation and purification of the Sertoli cells together comprise or include the steps of:
  - a) surgical removal,
  - b) digestion with trypsin[,]and Dnase; and
  - c) washing and culturing of ~~thesaid~~ cells.

11. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 1, wherein the method further includes the additional step of:  
[5]8) virological and microbiological testing and/or monitoring of thesaid aggregates and/or components thereof.

12. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 1, wherein the method additionally or alternatively includes a pre-step before step 1) that comprises of virological monitoring and/or testing of one or both of thesaid islets or said Sertoli cells.

13. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 1, wherein the method additionally or alternatively includes a pre-step before step 1) of virological monitoring and/or testing of the piglet donors.

14. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 1, wherein said islets and Sertoli cells are derived from the same herd or from the same donor piglet(s).

15. (Currently Amended) ~~A~~ The method of claim 14, wherein the said donor piglet(s) are about one week old donors.

16. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 14, wherein thesaid donor piglet(s) are monitored and/or tested for infectious agents.

17. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 14, wherein said donor piglet(s) are from a New Zealand pig herd.

18. (Currently Amended) ~~A method of any one of the preceding claims~~ The method of claim 1, wherein the step of the formation of the aggregate additionally or alternatively includescomprises the preservation of the original characteristics and/or native structure

of the islets.

19. (Currently Amended) An aggregate of porcine islets with Sertoli cells prepared substantially according to ~~a method of any one of claims 1 to 18~~the method of claim 1.
20. (Currently Amended) A method of treating a patient suffering from diabetes mellitus comprising ~~or including~~ the steps of:
  - 1) preparing one or more aggregates of porcine islets with Sertoli cells ~~prepared~~ substantially according to ~~a method of any one of claims 1 to 18~~the method of claim 1; and
  - 2) implanting or otherwise administering one or more of said aggregates to ~~the~~said patient.
21. (Currently Amended) ~~A~~The method of claim 20, wherein said step of implanting or administering the aggregate may be by:
  - (a) encapsulation of the aggregate in a suitable biocompatible material;
  - (b) confinement into a suitable device;  
~~matrix preparations including preparation of gelatin, collagen, and natural carbohydrate polymers.~~  
~~— plasma thrombin clot autologous plasma clots produced with allogeneic thrombin.~~
  - (c) inclusion in a matrix that comprises gelatin, collagen, or natural carbohydrate polymers; or
  - (d) inclusion in a plasma thrombin clot or an autologous plasma clot produced with allogeneic thrombin.
22. (Currently Amended) ~~A~~The method of claim 21, wherein ~~the~~said biocompatible

material iscomprises a suitable alginate.

23. (Currently Amended) AThe method of any one of claims 21 to 22claim 21, wherein the said suitable device is a vascularized tube.
24. (Currently Amended) A device for implantation into a recipient suffering from diabetes mellitus, wherein said the device incorporating aggregates of porcine pancreatic islets and porcine Sertoli cells, the aggregates being, or possessing the characteristics of,comprises the aggregates of claim 19 an aggregate of porcine islets with Sertoli cells prepared substantially according to the method of claim 1.
25. (Currently Amended) AThe device of claim 24, wherein said device incorporating the aggregates may be one of :
  - [ - ](a) a suitable biocompatible material as a capsule;
  - [ - ](b) a vascularized tube;
  - a matrix preparation including preparation of gelatin, collagen, and natural carbohydrate polymers;
  - a plasma thrombin clot autologous plasma clots produced with allogeneic thrombin.

(c) a matrix preparation comprising gelatin, collagen, or natural carbohydrate polymers; or

(d) a plasma thrombin clot or an autologous plasma clot produced with allogeneic thrombin.
26. (Currently Amended) AThe device of claim 25, wherein said biocompatible material iscomprises a suitable alginate.
- 27-28. (Canceled)